

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
BuSang Liu et al.

Application No.: 10/811,420

Confirmation No.: 2642

Filed: March 26, 2004

Art Unit: 1614

For: TOPICAL COMPOSITION FOR
TRANSDERMAL ADMINISTRATION

Examiner: Zohreh VAKILI

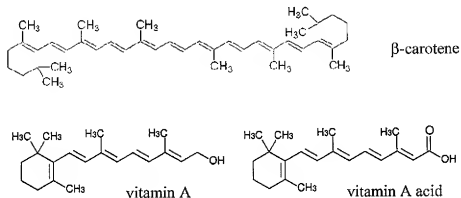
PRE-APPEAL BRIEF REQUEST FOR REVIEW

Claims 1-9 are non-obvious over Murad (U.S. Patent No. 6,630,163), in view of Murad (U.S. Patent No. 5,962,517), and further in view of Gildenburg et al. (U.S. Patent No. 6,217,852).

As discussed in the present specification, prior art compositions often include vitamin A or vitamin A acid. Vitamin A acid may make the skin sensitive to light and may lead to dry skin, red swelling, itching and dermatitis. (see paragraph [0012] in U.S. 2004/0228908). Inventors of the present invention have found that carotene does not have these adverse effects, while maintains the benefits of vitamin A or vitamin A acid. Therefore, a composition of the invention contains carotene, but is substantially free of vitamin A or vitamin A acid.

The examiner asserts that because carotene is a precursor of vitamin A, if a composition contains carotene, this composition is not substantially free of vitamin A or vitamin A acid. The Examiner seems to hold that carotene is equivalent to vitamin A or that carotene is readily converted into vitamin A. This logic is flawed because a precursor is not the same as its product, even though the precursor may be converted into the product by a series of enzymes. By ignoring the fact that a precursor and a final product are different chemical entities, the Examiner's position is not supported by scientific principles.

Although carotene can be converted into vitamin A via multiple enzymatic steps inside our body, carotene is distinct from vitamin A. (see structures shown below). Therefore, a topical composition comprising carotene is distinctly different from that containing vitamin A, and vice versa.



The fact that carotene and vitamin A are different chemical entities is well established. For example, a report by the scientists at the U.S. Department of Agriculture (USDA) (Agriculture Research, March 2001, p. 12-13, a copy of which was submitted with the Reply filed on December 4, 2007) shows that in some individuals, the conversion from carotene to vitamin A in human body can take more than 3 days and the efficiency can be extremely low (8%). (p. 12, right column, lines 14-16). Even in subjects who have more efficient enzymes, the process took 12 hours to achieve 30% conversion. (p. 12, right column, lines 10-13). Note that carotene was taken orally by the individuals in these experiments. If the carotene were applied topically, the bioavailability and conversion would most likely be even more inefficient. In any event, these results clearly rebut Examiner's implicit assumption that carotene is equivalent to vitamin A or that carotene is readily converted to vitamin A.

The patentability of a composition should be judged based on combination of its components as claimed, not how it could have been converted inside our body. Furthermore, these are topical compositions to be used on the skins. Carotene will not encounter the necessary enzymes that convert carotene into vitamin A or vitamin A acid.

That one skilled in the art would not consider that vitamin A derivatives include carotene is also evident in the Murad '517 patent cited by the examiner. The acne reducing composition disclosed in Murad '517 patent includes a vitamin A source and a carotenoid component, among other things. If a vitamin A source includes a carotenoid, or vice versa, then they will not be listed separately.

Applicant respectfully submits that a combination of Murad '517, Murad '163, and Gildenburg '852 fails to teach or suggest all limitations of the claims in the present application. Specifically, they fail to teach or suggest at least one limitation of the claims of the invention, i.e., "wherein the composition is substantially free of vitamin A or vitamin A acid."

Murad '517 teaches a pharmaceutical composition for the treatment of acne comprising an acne reduction component. The acne reduction component is a vitamin A source, a carotenoid component, a vitamin B₆ source, and a zinc component. (Col. 3, lines 41-43; 56-58). This composition specifically includes a vitamin A source and a carotenoid component, indicating that Murad recognizes that these are distinct chemical components. Further, Murad '517 teaches "Vitamin A is necessary for healthy skin cell growth and tissue formation." (Col. 5, lines 60-61). Therefore, Murad '517 teaches away from a topical composition substantially free of vitamin A or vitamin A acid. At the minimum, Murad '517 fails to teach or suggest a topical composition substantially free of vitamin A or vitamin A acid.

Murad '163 teaches a dermatological agent including at least one fruit extract from pomegranate. (Col. 6, lines 26-28). The composition may further comprise a moisturizing agent, a sunscreen or sunblock component, antioxidants, etc. The antioxidants may be a catechin-based preparation, a vitamin A source, a ginkgo biloba extract, a silymarin source, a quercetin compound, a vitamin C source, a carotenoid, or a mixture thereof. (Col. 7, lines 8-11). The vitamin A is typically present in an amount from about 5 to 50 weight percent. (Col. 14, lines 57-59). Again, Murad '163 does not teach or suggest a composition substantially free of vitamin A or vitamin A acid.

Gildenburg teaches personal cleansing compositions having photoprotective agents. Specifically, Gildenburg et al. taught a composition for use as a sunscreen applied during washing. The composition includes photoprotective agents of the organic type (e.g., octylmethoxy cinnamate and oxybenzone), the inorganic type (e.g., titanium oxide and zinc oxide), or combinations of the organic and inorganic agents. (Abstract) Examiner cites Gildenburg for the teaching of surfactants. Similarly, Gildenburg fails to teach or suggest a composition substantially free of vitamin A or vitamin A acid.

Although obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention, none of the cited references provide teaching, suggestion, or motivation to produce a topical composition substantially free of vitamin A or vitamin A acid. This is because none of these references recognize the drawback of having vitamin A or vitamin A acid in a topical composition.


In view of the above, a combination of Murad (U.S. Patent No. 6,630,163), Murad (U.S. Patent No. 5,962,517), and Gildenburg et al. (U.S. Patent No. 6,217,852) fails to teach or suggest each and every limitation of the claims of the instant invention.

Conclusion

In view of the above, the Examiner has failed to establish a prima facie case of obviousness for any of the pending claims. Accordingly, a favorable decision from the panel is respectfully requested. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 17469/004001).

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Respectfully submitted,

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